UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHRISTEL BILLHOFER, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

v.

FLAMEL TECHNOLOGIES, SA, STEPHEN H. WILLARD, and RAFAEL JORDA,

Defendants.

1:07-cv-09920 (CSH)

MEMORANDUM OF DECISION AND ORDER

HAIGHT, Senior District Judge:

Plaintiff Christel Billhofer ("Billhofer") filed this putative class action alleging claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, alleging that both the individual defendants and the defendant corporation, Flamel Technologies, SA ("Flamel"), disseminated statements that were false, either by direct misrepresentation or by omission, and that she relied on those false statements to her detriment. Defendant Stephen H. Willard ("Willard") was at all relevant times the Chief Executive Officer of Flamel, and Defendant Rafael Jorda was at all relevant times the Chief Operating Officer, Executive Vice President and Director of Manufacturing and Development of Flamel. *See* Am. Compl. ¶¶ 5-6.[1]

Flamel has moved to dismiss this action under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. Def.'s Mot. To Dismiss [doc. #11]

1. According to defendant Flamel's brief in support of its Motion To Dismiss, "Stephen H. Willard and Rafael Jorda, who are officers of Flamel and reside in France, are named as defendants but have never been served with process." Def.'s Mem. [doc. #12] at 1 n.1. Defendant Kenneth Lundstrom, the Director of Research at Flamel, and defendant Rémi Meyrueix, the Scientific Director at Flamel, were described in the original Complaint [doc. #1] at paragraphs 12-13 as officers of Flamel, but are not named as defendants in the Amended Complaint and have been dropped from the caption.

at 2. Flamel contends that the relevant statement upon which Billhofer allegedly relied was not misleading, did not give rise to a duty of disclosure, and was immaterial as a matter of law as a vague expression of corporate optimism. Flamel also contends that Billhofer has not adequately pled "scienter" as required by relevant case law and the Private Securities Litigation Reform Act (PSLRA). Flamel argues that Billhofer cannot establish scienter because the complaint fails to specify benefits to the defendants, and the proposed fraudulent scheme was doomed to failure from its conception, depriving defendants of any "motive" to commit fraud. Flamel argues that, alternatively, Billhofer cannot establish scienter through "strong circumstantial evidence of conscious misbehavior or recklessness" because facts pled in the complaint do not rise to such a level.

For the reasons stated below, defendant Flamel's Motion To Dismiss is DENIED.

I. Plaintiff's Allegations

The following factual allegations in plaintiff's Amended Complaint [doc. #10] are accepted as true for the purposes of this motion to dismiss:

Flamel Technologies develops "polymer-based delivery technologies." These products allow Flamel's partners — other pharmaceutical companies — to create "extended release" versions of their own drugs. Am. Compl. ¶ 13. The Amended Complaint alleges:

> 14. Flamel's lead product is COREG CR (controlled release) which is used in the treatment of moderate to severe congestive heart failure, left ventricular dysfunction following myocardial infarction and hypertension. COREG CR was introduced by Flamel and its marketing partner GlaxoSmithKline ("GSK") in March 2007.
>
> 15. Prior to the introduction of COREG CR, GSK marketed and sold COREG IR, which required users to take one pill twice-a-day while COREG CR is only required to be taken once-a-day. The successful introduction of COREG CR was critical to GSK

> and Flamel as the companies needed to transition users to COREG CR from COREG IR before generic competition entered the market, which was expected to occur in late 2007.

Id. ¶¶ 14-15.

According to press reports quoted in the Amended Complaint, the success of the new version of COREG would depend on convincing doctors to prescribe it and convincing insurance companies to pay for it. Both of those things, in turn, would require a clinical study to demonstrate that the new version produced better health outcomes than the original, twice-a-day formulation. *Id.* ¶ 31.

The Amended Complaint also contains several allegations about one such clinical trial that was conducted "by Flamel and GSK," with the strong suggestion that the study was conducted by those entities *together*. Am. Compl. ¶ 17.

> 18. In order to prove the benefits of COREG CR, GSK and Flamel commenced a clinical trial to measure the differential compliance, quality of life and satisfaction with medication in chronic heart failure patients taking COREG IR vs. COREG CR (the "CASPER Trial"). The primary outcome of the CASPER Trial was pill-taking compliance.
>
> 19. By no later than the start of the Class Period, the CASPER Trial was complete and the results were made known to GSK and Flamel. An abstract of the CASPER Trial was required to be submitted to the *Journal of Cardiac Failure* by no later than April 9, 2007. To meet this deadline, GSK and Flamel were required to complete the CASPER Trial, analyze the associated data, and draw conclusions therefrom — all sufficiently in advance of the submission date.
>
> 20. The abstract of the CASPER Trial, which was submitted to the *Journal of Cardiac Failure*, concluded that switching from COREG IR to COREG CR "was not associated with better drug taking compliance. . . ." **Thus, the primary selling point for COREG CR was not supported by the CASPER Trial.**

Am. Compl. ¶¶ 18-20 (ellipsis and emphasis in original). Later, when the results of this Trial were made public, the price of Flamel's stock plummeted, allegedly causing Billhofer and those similarly situated to suffer damages. *Id.* ¶¶ 21, 33.

Plaintiff Christel Billhofer purchased 900 shares[2] of Flamel on April 24, 2007. Am. Compl. ¶ 3; Certification, Am. Compl. app. [doc. #1 at 16-17]. By that particular date, Flamel had issued only one public statement relevant to this action. Specifically, on March 23, 2007, Flamel issued a press release announcing the nationwide availability of COREG CR. According to Billhofer, defendant Willard made the following comment in the press release:

> We are pleased that COREG CR™ will now be available to patients in the U.S. for the treatment of these three serious conditions. COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology as well as in our MEDUSA® technology platform for the delivery of proteins and peptides. *Interest in both technologies has never been higher.*

Am. Compl. ¶ 22 (emphasis added).

In later statements, the company and other individual defendants make far more specific statements about COREG CR, all of which were positive.[3] However, for reasons described *infra*, those statements are not relevant to determining the loss that Billhofer suffered, since her stock

---

2. As Flamel explains in its brief, stock in this foreign company is traded in the United States as an "American Depository Receipt," or ADR, which is a "means by which American investors hold and trade equity interests in foreign companies." Def.'s Mem. at 3 n.2 (quoting *Gas Natural v. E.On AG*, 468 F. Supp. 2d 595, 596 n.1 (S.D.N.Y. 2006)).

3. For example, on May 7, 2007, defendant Willard commented on financial results and said that COREG CR's launch had been an "early success" with "very positive" feedback. "Physicians understand that the once-daily formulation of COREG CR offers key advantages to patients. It is well established that once-daily medications lead to greater patient compliance; non-compliance is one of the leading causes of hospitalization in heart failure patients." Am. Compl. ¶ 24 (emphasis deleted).

ownership position never changed after the initial statement on March 23, 2007 — she neither bought nor sold any Flamel shares between her initial purchase and the filing date for this action.

Nevertheless, Billhofer argues that even ignoring the defendants' subsequent statements about COREG CR, the statements made prior to April 24, 2007 were sufficiently "positive" to "create[] an obligation to disclose the adverse conclusion of the CASPER Trial which materially undermined Defendants' claims about the positive attributes of the Company's proprietary technologies." Am. Compl. ¶ 28.

On or about August 23, 2007, the *Journal of Cardiac Failure* published the abstract that allegedly had been drafted months earlier, describing the results of the CASPER Trial, and as a result, the price of Flamel ADRs "plummeted." Am. Compl. ¶ 21. This lawsuit was filed less than three months later, on November 9, 2007. The putative class consists of "all purchasers of the American Depository Receipts ("ADR") of Flamel between March 23, 2007 and August 22, 2007." *Id.* ¶ 1.

II. Standard of Review

A. Motion To Dismiss

The court's focus on a motion to dismiss under Fed. R. Civ. P. 12(b)(6) is "not whether the plaintiff will ultimately prevail but whether the plaintiff is entitled to offer evidence to support the claims," *Villager Pond, Inc. v. Town of Darien,* 56 F.3d 375, 378 (2d Cir. 1995).

Generally speaking, a motion to dismiss requires the court to accept all well-pleaded facts as true and to consider those facts in the light most favorable to the plaintiff, *Patane v. Clark,* 508 F.3d 106, 111 (2d Cir. 2007). The factual allegations made in the complaint "must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 555 (2007). This requires

the complaint to contain "enough fact to raise a reasonable expectation that discovery will reveal evidence" of the plaintiff's claim. *Id.* at 556. "[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads *factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009) (citing *Twombly*; internal quotation marks omitted; emphasis added). The Supreme Court distinguishes between factual content and conclusory allegations, stating that when "bare assertions . . . amount to nothing more than a formulaic recitation of the elements" of a claim, then "the allegations are conclusory and not entitled to be assumed true." *Id.* at 1951 (citing *Twombly*; internal quotation marks omitted). The Court has said that "[d]etermining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950.

To state a claim surviving dismissal under Rule 12(b)(6), a claim under Section 10(b) of the Securities Exchange Act of 1934[4] "must allege that the defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 105 (2d Cir. 2007); *accord Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, —, 128 S.Ct. 761, 768 (2008).

4. Codified at 15 U.S.C. § 78j. The standard for stating such a claim is spelled out more explicitly in the attendant Rule 10b-5, promulgated by the Securities and Exchange Commission, 17 C.F.R. § 240.10b-5.

However, in a securities fraud action, heightened pleading requirements apply, for two reasons. First, because her complaint alleges fraud, Billhofer's claims must meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b).[5] Second, a plaintiff must "do more" under the Private Securities Litigation Reform Act's heightened pleading instructions, which were "enacted in 1995 as a check against abusive litigation by private parties." *South Cherry Street, LLC v. Hennessee Group LLC*, 573 F.3d 98, 110 (2d Cir. 2009) (internal quotation marks, brackets, and citation removed).

Specifically, under PSLRA § 21D(b)(1)-(2), the complaint must "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading," and "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(1)-(2).

"The requisite state of mind in a section 10(b) and Rule 10b-5 action is an intent to deceive, manipulate, or defraud." *ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) [hereinafter "*ECA & Local 134*"] (citations and internal quotation marks omitted). "A plaintiff can establish a strong inference of fraudulent intent in two ways: either (a) by alleging facts to show that defendants had both motive and

---

5. More specifically,

> [a] securities fraud complaint based on misstatements must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent. Allegations that are conclusory or unsupported by factual assertions are insufficient.

ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007).

Flamel does not focus its argument on insufficiency under Rule 9(b) with respect to allegations of fraud; rather, it argues that the complaint fails to meet the heightened pleading requirements of the PSLRA.

opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 267 (2d. Cir. 1996) (citations and internal quotation marks omitted); *see also ECA & Local 134*, 553 F.3d at 198 (citing the same two-part standard).

To raise a strong inference under the first alternative, motive and opportunity, a plaintiff must allege that the company or its officers "benefitted in some concrete and personal way from the purported fraud." *ECA & Local 134*, 553 F.3d at 198. The *ECA & Local 134* court went on to clarify that concept:

> Motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute "motive" for purposes of this inquiry. Rather, the "motive" showing is generally met when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit. Alternatively, if Plaintiffs cannot make the "motive" showing, then they could raise a strong inference of scienter under the "strong circumstantial evidence" prong, "though the strength of the circumstantial allegations must be correspondingly greater" if there is no motive. At least four circumstances may give rise to a strong inference of the requisite scienter: where the complaint sufficiently alleges that the defendants (1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to monitor.

Id. at 198-99 (citations and some internal quotation marks omitted).

As for the second alternative, "recklessness is a sufficiently culpable mental state for securities fraud in this circuit. Recklessness is defined as at the least, an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or

so obvious that the defendant must have been aware of it." *Id.* at 198 (internal quotation marks, ellipses, and citations omitted).

In *South Cherry*, the Second Circuit said:

> To meet the "strong inference" standard, it is not sufficient to set out "facts from which, if true, a reasonable person *could* infer that the defendant acted with the required intent," for that gauge "does not capture the stricter demand Congress sought to convey in § 21D(b)(2)." Rather, "*[t]o qualify as 'strong'* within the intendment of § 21D(b)(2), ... *an inference of scienter* must be more than merely plausible or reasonable — it *must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.*"

573 F.3d at 110-11 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S.Ct. 2499 (2007)) (emphasis in *South Cherry*; citations omitted). In other words, the court must consider not only inferences urged by the plaintiff, "but also competing inferences rationally drawn *from the facts alleged.*" *Tellabs*, 551 U.S. at 314 (emphasis added).

> In sum, "[a] plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference." And in determining whether this standard has been met, the court must consider whether "*all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."

South Cherry, 573 F.3d at 111 (quoting *Tellabs*, 551 U.S. at 328, 323) (omission in *South Cherry*; emphasis in *Tellabs*; citations omitted).

III. Discussion

A. Material Misstatement or Omission

The first element plaintiff's complaint must plead is that the defendants "made misstatements or omissions of material fact," which must be alleged with particularity.

1. Material Misstatement: The March 23, 2007 Press Release

The March 23, 2007 statements are the only ones relevant to plaintiff's claim. That is because in order to be actionable under Rule 10b-5, any misstatements or omissions must be a proximate cause of the plaintiff's reliance and damages, and it is an inescapable rule of causality that a cause must precede its effect.[6] Thus, in order for any of Flamel's statements or omissions to have been a cause of the plaintiff's reliance — proximate or otherwise — they must have been made *prior* to her purchase of the company's shares on April 24, 2007.[7]

Flamel argues that the March 23, 2007 disclosure "did not refer to patient compliance rates or COREG CR's sales potential." Def.'s Mem. [doc. #12] at 5; *see also id.* at 8. "Rather, because these statements do no more than discuss the historical performance of COREG CR's introduction — whose accuracy is not challenged — they cannot, as a matter of law, be found misleading for omitting discussion of potential future sales performance." *Id.* at 8.

Plaintiff's version of events is understandably different.

> On March 23, 2007, Flamel, however, touted the drug's "success," while armed with the knowledge that the primary selling point for COREG CR (compliance) had ***failed***, thus calling into question the viability of COREG CR's marketability and also the very value of the Company's technology. *While Flamel had no duty to release any press articles about COREG CR, once Flamel decided to discuss the success or failure of the drug, it was required to be*

---

6. I leave to philosophers discussions of "reverse causality," time travel, and the like.

7. Flamel argues that if its March 23, 2007 statement is not actionable, "plaintiff may not assert a § 10(b) claim for herself or on behalf of anyone else." Def.'s Mem. at 7 (citing cases). The question of Billhofer's ability to represent subsequent purchasers must be left for a motion to certify a class under Fed. R. Civ. P. 23.

Nevertheless, Billhofer effectively concedes that the viability of her case turns on the March 23, 2007 statement, when she argues that she "can represent purchasers who purchased throughout the Class Period" simply "[*b*]*ecause Plaintiff has properly alleged a misstatement or omission prior to her purchase of the Company's ADRs*." Def.'s Mem. [doc. #12] at 10 (emphasis added) (citing cases).

> *completely forthcoming* and any description of the drug as a "success" was clearly misleading.

Pl.'s Mem. in Opp'n [doc. #15] at 2-3 (second emphasis added).

The dispute over the word "success" intensifies even further in Flamel's reply brief, which argues again that the word "success" could not have misled a reasonable investor because "it *cannot* be understood as referring either to patient compliance rates for COREG CR or to the product's market potential — and thus did not trigger a duty to disclose the CASPER trial results (even if those results had been known by Flamel)." Def.'s Reply [doc. #16] at 3 (emphasis added).[8] Furthermore, Flamel argues that *the market* must not have understood the word "success" in the March 23, 2007 press release as anything "but implausible speculation," because, among other things, "the Amended Complaint fails to site a single securities analyst who understood Flamel's use of 'success' to mean that the CASPER trial had found improved patient compliance rates for COREG CR." Def.'s Reply at 4.

While Flamel seeks to minimize the import of the March 23, 2007 press release, I find its arguments to be at odds with the plain language of that document.[9] To recall, the March 23 press release contained the following comment from Defendant Willard:

> We are pleased that COREG CR™ will now be available to patients in the U.S. for the treatment of these three serious conditions. COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology as well as in our MEDUSA®

8. Flamel argues instead that its "use of the term 'success' *could* reasonably be understood as referring only to the technical attributes of Flamel's 'micropump' technology." Def.'s Reply at 3-4 (emphasis added).

9. Likewise, I find the absence of particularized pleadings regarding specific "securities analyst[s]" to be irrelevant. Nothing in PSLRA jurisprudence requires a plaintiff to identify a specific, individual "securities analyst" who claims to have been misled by a particular misstatement.

> technology platform for the delivery of proteins and peptides. Interest in both technologies has never been higher.

Am. Compl. ¶ 22.

The trouble with this press release is not merely the word "success," which is certainly troublesome in its own right, but rather the use of that term coupled with the much more definite statement that "[i]nterest in both technologies has never been higher." *Id.* According to the same March 23, 2007 press release, Flamel had partnered with GlaxoSmithKline which "yesterday announced the U.S. nationwide availability of COREG CR . . . for use in treating three cardiovascular conditions." *Id.* Regardless of whether Flamel had access to the results of the CASPER study, it would have been reasonable for an investor to think that GSK as the developer of COREG CR might have access to those results.[10]

Thus, the statement that "[i]nterest in both technologies has never been higher" necessarily suggests that *GlaxoSmithKline*'s interest in those technologies was also higher — a fact that would certainly not be the case if GSK knew that the COREG CR trial had produced disappointing results. So while the March 23, 2007 press release would not have necessarily implied that Flamel already possessed the results of the CASPER study and that those results were positive, its omission of any contrary statements *does* necessarily imply an opposite conclusion: that Flamel *and* its partner, GSK, were not in possession of material information — such as a negative outcome in the CASPER study — that would detract from the "success" of

10. This is especially true considering that eventually those results were GSK's to release. *See* Am. Compl. ¶ 27 (quoting defendant Willard as telling analysts that the results of the CASPER study were "for GSK to be able to tell people about" at its discretion).

COREG CR or cause "interest in both technologies" to have moved in any direction other than "higher."[11]

Flamel is correct in arguing that at least some investors must not have interpreted the March 23, 2007 press release to suggest that COREG CR "had obtained 'success' in the supposedly critical area of patient compliance rates," because "as pled in the Amended Complaint, securities analysts, through May and August 2007, continued to ask when the CASPER trial results would be published and what they would show." Def.'s Reply at 5 (citing Am. Compl. ¶¶ 25, 27). But that does not deprive the statement of its materiality. It would be reasonable for an investor or securities analyst to assume that GSK and/or Flamel had access to the results prior to releasing them, and knew what the results were.

Continuing with its emphasis on the word "success," Flamel also asserts that the March 23, 2007 press release was a "quintessential example of [] immaterial corporate puffery." Def.'s Reply at 5. While "expressions of puffery and corporate optimism do not give rise to securities violations," *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004); *see also In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) (collecting cases), I cannot agree that this characterization applies to the case at bar. The March 23, 2007 press release represented that COREG CR had just become available nationwide, and that the COREG CR "program" was a "success," leading to the claim that "[i]nterest in both technologies has never been higher."

---

11. I accept for the purposes of argument that "disclosure of accurate historical data does not become misleading even if less favorable results might be predictable by the company in the future." *In re Duane Reade Inc. Sec. Litig.*, 02 Civ. 6478 (NRB), 2003 WL 22801416, at *6, 2003 U.S. Dist. LEXIS 21319, at *23 (S.D.N.Y. Nov. 25, 2003); *see also* Def.'s Mem. at 8-9 n.6 (citing a handful of cases in support of this proposition). Nevertheless, I cannot see how proclaiming that "[i]nterest in both technologies has never been higher" could be merely a "disclosure of accurate historical data" — especially if GSK had recently become aware of the disappointing results from the CASPER trial.

Taken together, as the authors undoubtedly intended, these assertions "were neither 'vague' nor 'non-specific' pronouncements that were incapable of 'objective verification.'" *In re Moody's Corp. Sec. Litigation*, 599 F. Supp. 2d 493, 509 (S.D.N.Y.,2009) (quoting *In re Tower Auto. Sec. Litig.*, 483 F. Supp. 2d 327, 336 (S.D.N.Y. 2007)). Even if companies measure "interest" in their products in a variety of ways, they cannot then make categorical claims that interest has *never been higher* without some basis for that statement. As I have already said, it stretches credibility to imagine that when GSK lost its primary marketing angle for COREG CR, it nevertheless continued to maintain a similar (or "higher") level of "interest" in Flamel's technologies.

2. Material Omission: Silence Following the March 23, 2007 Press Release

More importantly, even if the March 23, 2007 press release did not amount to a material misstatement, at the very least it created a continuing duty to disclose the CASPER results, once those results became known to Flamel, or once those results caused GSK's "interest" in Flamel's technologies to lessen.

The rule that speaking on a subject creates a continuing duty to avoid rendering prior public statements misleading in a material way comes from a line of cases that includes *In re Time Warner, Inc. Sec. Litig.*, 9 F.3d 259 (2d Cir. 1993). In that case, the Second Circuit made several observations that are highly salient in a context similar to this one — a motion to dismiss for insufficiency under Rule 12(b)(6).

> A duty to disclose arises whenever secret information renders prior public statements materially misleading, not merely when that information completely negates the public statements. Time Warner's public statements could have been understood by reasonable investors to mean that the company hoped to solve the *entire* debt problem through strategic alliances. Having publicly hyped strategic alliances, Time Warner may have come under a

> duty to disclose facts that would place the statements concerning strategic alliances in a materially different light.
>
> . . . We do not hold that whenever a corporation speaks, it must disclose every piece of information in its possession that could affect the price of its stock. Rather, we hold that *when a corporation is pursuing a specific business goal and announces that goal as well as an intended approach for reaching it, it may come under an obligation to disclose other approaches to reaching the goal when those approaches are under active and serious consideration.* Whether consideration of the alternate approach constitutes material information, and whether nondisclosure of the alternate approach renders the original disclosure misleading, remain questions for the trier of fact, and may be resolved by summary judgment when there is no disputed issue of material fact. *We conclude here only that the allegations in this complaint of nondisclosure . . . are sufficient to survive a motion to dismiss.*

Id. at 268 (emphases added).[12]

At this early stage in litigation, I find that Billhofer has raised sufficient allegations of nondisclosure. Specifically, she has alleged that because of the publishing deadlines set by the *Journal of Cardiac Failure*, "GSK and Flamel" were "required to complete the CASPER Trial, analyze the associated data, and draw conclusions therefrom" before the submission date of April 9, 2007. Am. Comp. ¶ 19. If GSK and Flamel knew on April 9 that drug-taking compliance rates with COREG CR had not improved, and thus the "COREG CR program" was not quite the "success" originally envisioned, then the March 23, 2007 press release created an obligation upon Flamel to share that information.

B. Scienter

The Supreme Court has stated that in the context of an action for securities fraud, the requisite element of scienter is defined as "a mental state embracing intent to deceive,

12. Billhofer also cites a number of other cases standing for the same proposition. *See* Pl.'s Mem. at 8.

manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (further citations omitted); *accord South Cherry*, 573 F.3d at 108.[13] The Second Circuit has required that two questions must "be answered in the affirmative" with respect to scienter: "(1) whether the Complaint allege[s] facts sufficient to create a strong inference of scienter, and (2) whether an inference of scienter is at least as compelling as any opposing inference of nonfraudulent and nonreckless intent." *South Cherry*, 573 F.3d at 111. As stated *supra*, in order to create a strong inference of scienter, a complaint must show "either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *ECA & Local 134*, 553 F.3d at 198. I am also mindful of the Supreme Court's instruction in *Tellabs*, that "[t]he inquiry, as several Courts of Appeals have recognized, is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." 551 U.S. at 322-323 (emphasis in original).

1. Motive and Opportunity To Commit Fraud

Flamel argues that the complaint fails to allege a motive to commit fraud, because "plaintiff does not allege that Flamel sought to inflate its stock price . . . nor does plaintiff contend that the individual defendants . . . engaged in "suspicious" stock sales." Def.'s Mem. at 11. Billhofer responds that by withholding bad news, "the Company was able to initiate new partnerships with other drug companies to produce other drugs with Flamel's technology," and

13. That definition, provided by the Supreme Court, is somewhat at odds with the traditional legal definition, which is "[a] degree of knowledge that makes a person legally responsible for the consequences of his or her act or omission." Black's Law Dictionary, "scienter," (8th ed. 2004) *Id.* The term "scienter," in Latin, literally translates to the adverb "knowingly." *Id.*

"Flamel was also able to benefit from increased royalty revenues . . . during the time the market was unaware of the failures of COREG CR." Pl.'s Mem. at 12.[14]

But as Flamel points out in its reply, a properly pled motive requires that "the benefit alleged must be one that will accrue to the individual defendants; general benefits to the corporation will not suffice." *In re Initial Public Offering Sec. Litig.*, 358 F. Supp. 2d 189, 214 (S.D.N.Y. 2004); *see also ECA & Local 134*, 553 F.3d at 198 ("[T]he desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry."). It is clear to me that Billhofer has not alleged any "motive" rising above those common to all corporate officers. *See id.*

Because I agree with Flamel that Billhofer has not alleged sufficient motive to commit fraud, I do not need to reach its argument that, under plaintiff's theory of the case, "Flamel engaged in a fraudulent scame which was doomed to fail (because destined to be exposed within months)." Def.'s Mem. at 12; *but see* Pl.'s Mem. at 13 & n.7 (arguing that nowhere in the Amended Complaint is any allegation that Flamel's officers were ever *certain* that CASPER results would be published).

2. Conscious Behavior or Recklessness

Alternatively, if a plaintiff is unable to make adequate allegations of a motive and opportunity to commit fraud, that plaintiff may instead show "strong circumstantial evidence of conscious misbehavior or recklessness." *ECA & Local 134*, 553 F.3d at 198.

---

14. While the previous passage does not cite to any of the allegations in the Amended Complaint, I find that it portrays a series of inferences that can reasonably be drawn from the allegations in the pleading.

Flamel argues that "plaintiff must have 'specifically alleged defendants' knowledge of facts or access to information contradicting their public statements.'" Def.'s Mem. at 14 (quoting *Goplen v. 51job, Inc.*, 453 F. Supp. 2d 759, 773 (S.D.N.Y. 2006)). Flamel goes on:

> Wholly absent from the Amended Complaint is any factual averment — *e.g.*, a specifically identified document, public statement or percipient witness's testimony — linking knowledge of the results of the CASPER trial to anyone at Flamel, let alone an individual defendant, **before** the August 23, 2007 publication of the CASPER Trial abstract.

Def.'s Mem. at 15. Moreover, Flamel argues that "all the facts alleged are consistent with Flamel being unaware of [the CASPER] Trial results prior to publication," going on to cite several documents which I need not consider here.[15] Def.'s Mem. at 16. For example, the company's announcement on August 1, 2007 that "[w]e continue to manufacture [COREG CR microparticles] at the maximum rate," Am. Compl. ¶ 26, would be "wholly inconsistent with any inference that Flamel 'consciously' disregarded evidence that . . . undermined the 'primary selling point' for COREG CR." Def.'s Mem. at 17 (quoting Am. Compl. ¶ 20). Flamel once again argues that this is an "illogical scheme," which would negate an inference of intent to defraud. *Id.* (citing *In re Geopharma Inc. Sec. Litig.*, 399 F. Supp. 2d 432, 451-52 & n.147 (S.D.N.Y. 2005)).

Flamel's arguments in this respect are unavailing. The Amended Complaint clearly alleges facts that are more than sufficient to support an inference that Flamel knew *something* about the CASPER study results at *some point* during the "Class Period." *See, e.g.*, Am. Compl. 19 ("By no later than the start of the Class Period, the CASPER Trial was complete and the

15. Flamel wishes me to consider them because they are referred to in the Amended Complaint. Even if I were to consider them, I do not find these documents to be indicative one way or the other of Flamel's involvement in the CASPER study.

results were made known to GSK and Flamel. An abstract of the CASPER Trial was required to be submitted to the *Journal of Cardiac Failure* by no later than April 9, 2007. To meet this deadline, GSK and Flamel were required to complete the CASPER Trial, analyze the associated data, and draw conclusions therefrom . . . ."). Even if Flamel was unaware on March 23, 2007, when it issued the press release, it nevertheless chose to speak about the "success" of COREG CR, which created its ongoing duty to disclose information "whenever secret information render[ed] prior public statements materially misleading." *In re Time Warner*, 9 F.3d at 268. The facts as alleged by Billhofer give rise to a "strong inference" that the defendants "knew facts *or had access to information* suggesting that their public statements were not accurate." *ECA & Local 134*, 553 F.3d at 199.

3. Competing Inferences

The crux of this decision comes down to a classic "competing inference." Is it more reasonable to infer, given the facts accepted as true, that Flamel knew about the results of the CASPER trial prior to Billhofer's stock purchase on April 24, 2007? Or is it more reasonable to assume that Flamel was unaware of the trial's results not only on that date, but also until the day the results were published in the *Journal of Cardiac Failure*?

Billhofer argues that Flamel was not "an uninterested observer" in the CASPER trial of COREG CR.

> Flamel, along with GlaxoSmithKline ("GSK"), ran the clinical trial, and more importantly, the trial results had the ability to prove the viability of not just the ***only approved drug ever*** to use the Company's technology, but also the very viability and value of the Company's extended-release technology.

Pl.'s Mem. in Opp'n at 3.

While Billhofer's allegations of misstatements or omissions after April 24, 2007 are not relevant to determining whether or not she states a plausible claim for relief under section 10(b) and Rule 10b-5, they are useful and can be considered by the Court for another purpose: to assess the relative strength of the competing inferences that the parties argue with respect to Flamel's knowledge of the results from the CASPER Trial.

In this respect, I take special note of plaintiff's allegations concerning telephone conferences that occurred in May and August of 2007. I draw upon these statements not as evidence of whether Flamel knew of the results in March of 2007, but rather as a general indication of the company's willingness to be forthcoming in matters concerning its flagship drug.

Specifically, in May of 2007, the company issued a press release which claimed that "[t]he success of COREG CR is generating positive interest in the Micropump platform." Am. Compl. ¶ 24. The company also held a conference call with analysts and investors to review its financial results and operations, and during that call, defendant Stephen H. Willard, Flamel's CEO, was asked the following question by an analyst: "When do you expect the data from the ongoing trials you mentioned to become available and/or published . . . ?" *Id.* ¶ 25. Willard gave a rather long-winded response, which I excerpt here:

> I think there's a lot of data coming through. I mean, if you look at clinicaltrials.gov, if you look at a variety of other sources, you can see that there's a lot of data working through the system.
>
> *It will be within GSK's call as to how that data comes out.* They typically like to release data around some of the important meetings that occur throughout the year, but it will be for GSK to be able to talk about the timing of some of the studies.

Id. ¶ 25 (emphasis added).

Similarly, on August 1, 2007, Flamel issued a press release that again discussed COREG CR. "Regarding COREG CR, we believe it has strong ongoing potential *in all indications*. We continue to manufacture at the maximum rate and expect to do so even after the addition of new manufacturing capacity." *Id.* ¶ 26 (emphasis added). In a follow-up conference call the same day, once again, Flamel was asked by an analyst, "When do you expect the data from that [CASPER study] to be presented? GSK had indicated previously that it could be in the third quarter of this year." Again, Willard responded: "I — That's for GSK to be able to tell people about." *Id.* ¶ 27.

Notably absent from either of Willard's statements is any indication that the test results might be anything less than favorable for Flamel — even in early August, only three weeks before publication of the abstract that decimated Flamel's stock price, and which analysts were so eagerly awaiting. In a vacuum, such silence would be more than acceptable; but Flamel's positive statements about COREG CR change the nature of its obligations. In particular, Flamel had spent months trumpeting the compliance-related benefits of COREG CR for patients with both blood pressure problems and heart failure,[16] so its later suggestion that COREG CR had "strong ongoing potential *in all indications*," Am. Compl. ¶ 26 (emphasis added), demanded

---

16. The press release of May 7, 2007, also included the following statement:

> Physicians understand that the once-daily formulation of COREG CR offers key advantages to patients. It is well established that once-daily medications lead to greater patient compliance; non-compliance is one of the leading causes of hospitalization *in heart failure patients*. . . . Moreover, COREG CR has been observed to result in 24% fewer adverse events than immediate release Coreg in a crossover study conducted *in hypertension patients*.

Am. Compl. ¶ 24 (emphases added).

some sort of qualification, if Flamel had any reason to doubt the strong ongoing potential in all indications.

Moreover, if Flamel had in fact been completely in the dark about the results of the CASPER trial during both conference calls, it is entirely reasonable to expect that Flamel's representative would say as much. Instead, Willard remained silent, allowing the inference to linger in the air that Flamel knew the results of these studies, even if it was "within GSK's call" to decide when to release those results. As Billhofer points out:

> These opportunities were perfect for Willard to make sure the market was aware that Flamel had nothing to do with the trials, and had no information about the results, with a clear statement that "we don't know the results of the studies, we were not involved in them." . . . That Willard did not take these opportunities to denounce knowledge of the results is telling, and leads to an inference that defendants *did* know, and were merely putting the blame for the results not being made public on GSK, its marketing partner.

Pl.'s Mem. at 15.

C. Other grounds for dismissal

On this motion to dismiss, Flamel has not raised any other grounds for dismissing Billhofer's claim, such as an absence of loss or damages, an absence of reliance, or the applicability of any safe harbor provisions. *See* Am. Compl. ¶¶ 33, 35-36 (alleging those elements). Thus, I do not consider them as potential grounds for dismissal.

IV. Conclusion

Ultimately, the analysis on this motion to dismiss can be distilled to three inquiries. First, are plaintiff's allegations sufficient to render her claims plausible under *Twombly*? Second, are the alleged misstatements or omissions pleaded with sufficient particularity? And finally, are the allegations sufficient to raise a strong inference that the defendants acted with scienter, where

scienter can be established either through a motive and opportunity to defraud or strong circumstantial evidence of conscious misbehavior or recklessness?

In this case, the allegations clearly give rise to a plausible claim of securities fraud. The misstatements and omissions are identified with more than enough particularity to allow the defendant to respond during discovery, and they would clearly be material if the plaintiff's version of events is true. Plaintiff's allegations are insufficient to raise an inference of scienter through motive and opportunity. However, the pleadings have sufficiently alleged scienter through a strong inference of "conscious misbehavior or recklessness." Such misbehavior or recklessness can be strongly inferred from allegations that, if true, would provide strong circumstantial evidence that defendants knew of the result of the CASPER trial, and instead of disclosing those results, continued to indicate that compliance would be a key component of COREG CR's market appeal.

The factual allegations in plaintiff's Amended Complaint easily lift her claims to the level of "plausibility." Of course, discovery may reveal that Flamel had no knowledge of the results from the CASPER trial at any relevant point in this timeline. But that is the point of discovery: to see whether plaintiff's well-pleaded factual allegations are true.

Flamel's Motion To Dismiss [doc. #11] is DENIED.

It is SO ORDERED.

Dated: New York, New York
October 1, 2009

Charles S. Haight, Jr.
Senior United States District Judge